UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

JAMES PRICE, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. XBIOTECH, INC., JOHN SIMARD, and QUEENA HAN, Defendants.	§ § § § § § § § § § §	Civil Action No. 1:17-cv-1023 JURY TRIAL DEMAND

CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS

Plaintiff James Price ("Plaintiff") alleges the following based upon the investigation of counsel, which included a review of United States Securities and Exchange Commission ("SEC") filings by XBiotech, Inc. ("XBiotech" or the "Company"), as well as regulatory filings and reports, securities analyst reports and advisories by the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on beha1f of all investors who purchased or otherwise acquired XBiotech common stock between April 15, 2015, and April 20, 2017, inclusive (the "Class Period").

2. This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

3. XBiotech is a clinical-stage biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization or otherwise engineered.

4. The Company made materially false and/or misleading statements, misrepresenting the success of its European Phase III trials.

5. As the truth about the Phase III results was fully revealed to investors, the Company's share price fell $6.79 from a closing price on April 20, 2017, of $17.02 per share, to a close of $10.23 per share on April 21, 2017, ***a drop of approximately 40%.***

6. As noted in more detail herein, XBiotech's statements regarding the European Phase III study contained materially false information or omitted information necessary to make those statements not misleading. As a result, Plaintiff and other members of the Class purchased XBiotech securities at artificially inflated prices and thereby suffered significant losses and damages.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 27 of the Securities Act (15 U.S.C. § 77v).

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b) because certain of the acts alleged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in this District.

10. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly and/or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

11. Plaintiff purchased XBiotech securities within the Class Period and, as a result, was damaged thereby. Plaintiff's certification evidencing his transactions is attached hereto.

12. Defendant XBiotech is a British Columbia, Canadian corporation with its principal executive offices located at 8201 East Riverside Drive, Bldg. 4, Suite 100, Austin, Texas, 78744. Xbiotech's common stock trades on the NASDAQ under the ticker symbol "XBIT."

13. Defendant John Simard ("Simard") is the Company's chief executive officer ("CEO") and President.

14. Defendant Queena Han ("Han") is the Company's Vice President of Finance & Human Resources, Principal Financial Officer, and Principal Accounting Officer.

15. Defendants in Paragraphs 13-14 are collectively referred to herein as the "Individual Defendants."

16. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(d) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(e) was aware of or deliberately recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(f) approved or ratified these statements in violation of the federal securities laws.

17. Because of the Individual Defendants' positions within the Company, they had access to undisclosed information about XBiotech's business, operations, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations and performance), conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith.

18. As officers of a publicly held company whose securities were, and are, registered with the SEC pursuant to the federal securities laws of the United States, the Individual Defendants each had a duty to disseminate prompt, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

19. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of XBiotech's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional

investors, i.e., the market. Each Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each Defendant knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

20. Each of the Individual Defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of XBiotech securities by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme: (i) deceived the investing public regarding XBiotech's business, operations, management and the intrinsic value of its securities and (ii) caused Plaintiff and other shareholders to purchase XBiotech securities at artificially inflated prices.

SUBSTANTIVE ALLEGATIONS

A. Company Background

21. XBiotech is a clinical-stage biopharmaceutical company engaged in discovering and developing True Human™ monoclonal antibodies for treating a variety of diseases. True Human™ monoclonal antibodies are those which occur naturally in human beings—as opposed to being derived from animal immunization or otherwise engineered.

22. The Company concentrates on developing MABp1 (also known as Xilonix™, CA-18C3, CV-18C3, RA-18C3, T2-18C3 and Hutruo) (hereafter referred to as "Xilonix"), a therapeutic antibody which is supposed to neutralize interleukin-1 alpha (IL-1a). IL-1a is a pro-inflammatory protein produced by leukocytes and other cells, where it plays a key role in

inflammation. When unchecked, inflammation can contribute to the development and progression of a variety of different diseases such as cancer, vascular disease, inflammatory skin disease, and diabetes.

23. The Company completed its Phase I and II clinical trials for Xilonix as a treatment for cancer in 2012. In October 2012, XBiotech received a "fast track" designation from the FDA to develop Xilonix as a treatment for metastatic colorectal cancer.

24. On February 2, 2015, in connection with its initial public offering, XBiotech filed a registration statement on Form S-1 with the SEC. The registration statement was later amended on Form S-1/As with the SEC, with its last amendment filed on April 10, 2015 (collectively the "Registration Statement").

B. Material Misstatements and Omissions

25. The beginning of the Class Period is April 15, 2015. On April 14, 2015, the SEC declared XBiotech's Registration Statement effective. The Registration Statement contained material misrepresentations, including, in relevant part:

> **Current Clinical Activity**
>
> ***European Registration Study Oncology***
>
> Currently, we have a double-blinded, placebo-controlled Phase III registration study underway in Europe. Clinical sites are located in a number of different European Union member states, and the addition of sites in Russia is expected soon. The study aims to evaluate MABp1, or Xilonix™, as an anticancer therapy in patients with symptomatic colorectal cancer.
>
> The primary objective of this study is to assess the efficacy of Xilonix™ in reversing symptoms in patients with symptomatic colorectal cancer. By blocking a substance that helps tumors grow and spread, Xilonix™ therapy may not only slow tumor growth, but also may improve symptoms of muscle loss, fatigue, appetite loss, and pain in patients with colorectal cancer.
>
> ***The efficacy of the therapy will be measured by assessing the change in these symptoms for patients treated with Xilonix™ versus those treated with placebo***. Reversal of muscle loss will be assessed with a type of X-ray called a DEXA

> scanner. Improvement in pain, appetite loss, and fatigue will be measured with a questionnaire that is completed by patients enrolled in the trial.
>
> The study, which started in July 2014, will enroll at least 276 patients and is expected to be completed by mid-2015. As of March 3, 2015 about 122 patients had been enrolled. ***If the study endpoints are satisfactorily achieved, we expect to submit a registration package to the EMA and possible other foreign regulatory agencies.***

Emphasis added.

26. On December 7, 2015, XBiotech issued a press release releasing announcing positive results of its European Phase III trial for the treatment of colorectal cancer with Xilonix ("December 2015 Press Release"). The Company also attached the press release to a Form 8-K filed with the SEC ("January 2016 Form 8-K"). The Company made material misrepresentations in the press release, including, in pertinent part:

> This study, developed in collaboration with the EMA [European Medicines Agency], represents the first use of such a responder analysis in a controlled study for the development of an anticancer agent. **Xilonix** is thus the first anticancer agent evaluated using surrogate measures based on conservation of patient health status, and ***is believed to be the first anticancer therapy to demonstrate an ability to conserve or improve patient health status with treatment.***
>
> The Company plans to proceed with the marketing authorization process with the EMA and other jurisdictions.
>
> John Simard, CEO of XBiotech, stated, "***We are gratified to announce these findings with Xilonix. The ability of Xilonix to help improve the health of patients with cancer has been demonstrated. We look forward to seeking approval to deliver this unprecedented cancer agent to patients.***"

Emphasis added.

27. On January 8, 2016, XBiotech issued a press release releasing the results of its European Phase III trial for the treatment of colorectal cancer with Xilonix ("January 2016 Press Release"). The Company also attached the press release to a Form 8-K filed with the SEC

("January 2016 Form 8-K"). The Company made material misrepresentations in the press release, including, in pertinent part:

> Furthermore, while the study was not powered to demonstrate differences in serious adverse events (SAEs) between treatment and placebo groups, there was a 26% reduction in the risk of SAEs in the treatment arm relative to placebo (p=0.062). A treatment-related reduction in SAEs compared to placebo patients is a remarkable and important finding. An SAE is defined as a health-related event that is life-threatening, results in persistent or significant disability, or death. This may be the first report of a placebo controlled, randomized clinical study of an anticancer agent where there was reduced incidence of SAEs in a treatment arm. Finally, patients in the treatment arm were found to be 53% more likely to have stable disease compared to placebo at eight weeks (p=0.12).
>
> The trends toward reduced disease progression and a reduction in SAEs is compelling given the small patient population in the study. Together, the Company believes that these secondary findings corroborate the therapeutic value of the antibody in advanced, recalcitrant cancer.
>
> John Simard, CEO of XBiotech, stated, "***We believe this study serves as a confirmation that Xilonix is a unique anti-cancer agent for gently treating advanced, even fragile cancer patients***. We are also very proud that the study represents a milestone in the development of new clinical endpoints to assess efficacy of novel treatments that help heal patients with advanced disease."

Emphasis added.

28. The Company also filed the results as an exhibit to the Form 8-K. The results stated in pertinent part:

> The primary endpoint analysis involves use of a novel objective response rate used to compare response rates between treatment and placebo arms (Table 1). Primary endpoint analysis was performed as described above using a modified intent to treat (mITT) analysis that included 309 patients (102 in placebo and 207 Xilonix). Twenty-four patients that received neither a dose of placebo nor test article were excluded from this analysis. Based on this mITT analysis, a total of 19 patients (19%) in the placebo group were considered responders, compared to 68 patients (33%) in the Xilonix arm (p=0.0045). ***These results represented a 76% relative improvement in response rate between the Xilonix and placebo arms respectively***.
>
> Secondary analysis performed in this study included key pharmacodynamic measures (Table 1b) that have been positively correlated with survival in advanced cancer patients and had been observed with the test article in previous

> clinical findings. A 5-fold increase in platelet counts observed in the placebo group compared to the treatment arm was significant (p=0.003), with platelet counts maintaining close to baseline levels with antibody therapy.
>
> Although the study was not statistically powered to demonstrate differences in serious adverse events (SAEs) or stable disease between arms, these analyses are provided here due to the potential importance of these observations and the likely correlation between SAEs and the primary efficacy measure. A 26% relative risk reduction in the number of SAEs was observed in the treatment arm relative to placebo (p=0.062). Similarly, patients in treatment arm were 53% more likely to have stable disease (odds ratio 1.53 [95% CI 0.76 to 3.08]) compared to placebo at 8 weeks, although this difference did not reach statistical significance (p=0.12).

Emphasis added.

29. XBiotech issued a Form 10-K ("March 2016 Form 10-K") filed with the SEC on March 30, 2016. The Form 10-K was signed by Simard, Han, Bonanni, McKenzie, and Vasella. The Company made material misrepresentations about the European Phase III study. The Company stated in pertinent part:

> We received a fast track designation from the FDA in October 2012 to develop Xilonix™ as a treatment in the setting of metastatic colorectal cancer. The purpose of the fast track designation is to aid in the development, and expedite the review, of drugs that have the potential to treat a serious or life-threatening disease. Currently one Phase III study is underway in the United States for advanced refractory colorectal cancer. We recently completed another Phase III study in Europe for symptomatic colorectal cancer at the end of 2015. ***With the success of the European Phase III trial,*** we are now in the process of seeking marketing approval for MABp1 at the European Medicines Agency. If the United States Phase III trial is also successful, we will seek marketing approval for MABp1 at the U.S. Food and Drug Administration. Assuming such marketing approvals are obtained, we would distribute and sell this product through our own direct sales force or with a commercial partner.
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> * * *
>
> The study started in July 2014, completed in November 2015, and enrolled a total of 333 patients. The data cleaning, conducted shortly after the completion of the study, showed that fewer than expected patients were available for data analysis. We presented a short overview of these findings in a press release on November 23, 2015. As per the prospective analysis plan, the data from 24 patients was excluded from final analysis of the data as they discontinued study prior to receiving a single dose of either Xilonix™ or placebo. ***Because the study***

> ***endpoints were satisfactorily achieved***, we proceeded to submit a Marketing Authorization Application package to the European Medicines Agency (EMA) on March 7.
>
> * * *
>
> ***The Phase III study succeeded with respect to the prospective primary and secondary endpoints for Xilonix therapy in patients with advanced colorectal cancer***. A Marketing Authorization Application (MAA) has been submitted to the European Medicines Agency to seek approval for sale in Europe.
>
> * * *
>
> The Phase III primary endpoint to determine efficacy was based demonstrating an improved objective response rate for Xilonix therapy. For the 309 patients that received at least one dose of either Xilonix or placebo, ***there was a 76% relative improvement in objective response rate for patients receiving test article compared to placebo (p=0.0045).*** The secondary endpoints in the study were important were established prognosticators of overall survival, namely a measure of paraneoplastic thrombocytosis and systemic inflammation. Xilonix treated patients had an 80% reduction in thrombocytosis (p=0.003), and a 60% reduction in systemic inflammation (p=0.004) compared to placebo, respectively.
>
> * * *
>
> As of March 2016, XBiotech ***has achieved some significant milestones with its Xilonix™*** *a*nd 514G3 programs. Enrollment on a Phase III Symptomatic Colorectal Cancer Study has been completed and 333 subjects were enrolled. ***Because the study endpoints were satisfactorily met***, XBiotech decided to proceed with the submission of a Marketing Authorization Application to the European Medicines Agency, and possibly other foreign regulatory authorities. Additionally, the final patient for Phase I on a Staphylococcus Aureus Bacteremia Phase I and II Study with a brand new antibody therapy, 514G3, has been enrolled. Phase II will commence once it has been found the final enrolled patient is free of dose-related toxicities.

March 2016 Form 10-K, pp. 5, 13, 15, 46 (emphasis added).

30. On May 24, 2016, prior to the markets opening, XBiotech issued a press release announcing that the Company would be presenting the results of its European Phase III trial for the treatment of colorectal cancer with Xilonixits ("May 2016 Press Release"). The Company

also attached the press release to a Form 8-K filed with the SEC. The Company made material misrepresentations in the press release, including, in pertinent part:

> AUSTIN, Texas, May 24, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of next generation True Human™ antibody therapies, today said its upcoming presentation of pivotal Phase III data for Xilonix™, the Company's lead therapy developed for the treatment of advanced colorectal cancer, ***will include positive preliminary findings on survival***. The data are being presented July 2 at the 18th ESMO World Congress on Gastrointestinal Cancer in Barcelona, Spain.
>
> This will be the first presentation of the Phase III data at a major scientific congress. The primary endpoint of the study was clinical response rate (CRR) after 8 weeks of therapy in patients with advanced disease and multiple symptoms known to inversely correlate with overall survival. The CRR criteria were developed in collaboration with EMA's Scientific Advice Working Group to assess anti-tumor benefit of therapy based on control of these symptoms. Secondary endpoints evaluated paraneoplastic thrombocytosis and systemic inflammation, which also are known correlates for survival in colorectal cancer. As specified in the Phase III protocol, investigators also followed up with patients after study completion or discontinuation to assess their survival status. ***XBiotech will share positive preliminary results from this analysis showing a survival benefit correlating to the clinical response seen in this trial****;* this analysis is ongoing.

Emphasis added.

31. On July 2, 2016, XBiotech issued a press release disclosing European Phase III Data (the "July 2016 Press Release"). The Company made material false or misleading representations in the July Press Release. The Company stated in pertinent part:

> AUSTIN, Texas, July 02, 2016 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT), developer of next-generation True Human™ antibody therapies, today presented positive results from a pivotal Phase III trial of Xilonix™, the company's lead monoclonal (IgG1k) antibody immunotherapy for the treatment of advanced colorectal cancer (CRC). In the study, Xilonix-treated patients with advanced disease and multiple symptoms known to inversely correlate with ***overall survival experienced a 76% relative increase in clinical response rate (CRR)***, a novel measure of anti-cancer activity***, after 8 weeks of therapy compared to placebo (33% vs. 19%, respectively; p=.0045)***. In addition, clinical response correlated with improved overall survival. Among responders (in both treatment and placebo arms), clinical response was associated with a 2.7-fold increase in overall survival (11.5 versus 4.2 months in responders vs. non-

> responders, respectively). Overall survival was not compared between treatment arms because after 8 weeks, all patients were eligible to receive study drug. Treatment with Xilonix was well tolerated, with an adverse event profile comparable to placebo. The data were presented at the 18th European Society of Medical Oncology (ESMO) World Congress on Gastrointestinal Cancer in Barcelona, Spain.
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> * * *
>
> "In this first-of-its-kind study, not only did treatment with Xilonix demonstrate clinical benefit but it was also very well-tolerated, suggesting Xilonix has the potential to meet the real and urgent need for more effective, less toxic therapies for patients with advanced colorectal cancer," said Dr. Tamas Hickish, Chair of the Xilonix European Phase III Study and Consultant Medical Oncologist, Dorset Cancer Centre, Visiting Professor, Bournemouth University, UK. "In addition, this study provides evidence that novel endpoints based on symptom recovery can serve as a predictor of overall survival benefit and thus may be used to evaluate an anti-tumor agent in this disease."
>
> In addition to increased overall survival, responders gained more lean body mass compared to non-responders ($p<0.0007$), had reduced fatigue and pain ($p<0.001$) and improved appetite ($p<0.001$). Control of thrombocytosis and systemic inflammation (IL-6), ***which are known prognosticators of overall survival***, were also significantly improved in responders vs. non-responders ($p<0.0002$ and $p<0.0007$, respectively).
>
> * * *
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> "There is an urgent need for new forms of anti-tumor, disease-modifying cancer therapies that effectively control disease while being less toxic," said John Simard, XBiotech Founder, President and Chief Executive Officer. "***We believe these data demonstrate that our True Human monoclonal antibody targeting interleukin-1 alpha has the potential to meet this critical need.***"

Emphasis added.

32. The statements in paragraphs 25-31 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the actual results were inconclusive; (2) the Company misrepresented the endpoint used in the European Study; (3) the Company's claim of a 76% increase in

improvement was misleading and represented a relative improvement rate, (4) ultimately, the Companies' studies would not support the approval of the application with the EMA, and (5) as a result of the foregoing, Defendants' statements about its business and operations were materially false and misleading at all relevant times.

C. The Truth Begins to Emerge

33. On July 5, 2016, *TheStreet* published an article addressing the Company's July 2016 Press Release ("*TheStreet* July 5, 2016").[1] The article stated in pertinent part:

> Plenty of nonsensical, borderline crazy, excuses have been made for bad clinical trial results in my 15 years covering biotech, but XBiotech (XBIT) may have won the grand prize Saturday.
>
> Here's how the company attributed an increase in overall survival to its experimental colon cancer drug Xilonix in a phase III study.
>
> "Among responders (in both treatment and placebo arms), clinical response was associated with a 2.7-fold increase in overall survival (11.5 months vs. 4.2 months in responders vs. non-responders, respectively)."
>
> ***Claiming patients who respond to a drug are living longer than patients who don't respond is an old data-analysis trick usually attempted by companies when the real survival analysis -- drug vs. placebo or control -- shows nothing.***
>
> Inexperienced investors might be fooled by this clinically meaningless sleight of hand, but regulators in charge of reviewing and approving drugs aren't.
>
> XBiotech, however, goes next level with its survival claim by completely not caring if colon cancer patients in its phase III study were treated with Xilonix or a placebo.
>
> ***Responding colon cancer patients -- Xilonix or placebo, doesn't matter -- lived an average of 11.5 months!*** That's way better than the non-responding patients, who lived only an average of 4.2 months, XBiotech said.
>
> Absurd.

[1] *See* https://www.thestreet.com/story/13628326/3/xbiotech-cancer-drug-survival-claim-falls-apart-under-scrutiny.html.

XBiotech went on to say Saturday: "Overall survival was not compared between treatment arms because after 8 weeks, all patients were eligible to receive study drug."

In other words, XBiotech claims a credible survival analysis -- Xilonix vs. placebo -- was impossible to assess because patients randomized to placebo at the start of the trial crossed over to Xilonix after eight weeks.

This is just more not-so-clever misdirection by XBiotech. Patients crossing over from placebo to drug can muck with a survival analysis but the comparison can certainly still be performed. ***If the company knows "responders" to either Xilonix or a placebo, pooled together, are living an average of 11.5 months, then it's an easy task to separate them out and report proper survival data.***

The company is also staying silent about the ability of Xilonix to shrink tumors or delay tumor growth. Saturday's press release omitted any discussion of anti-tumor activity related to Xilonix compared to placebo, even though these endpoints were measured in the phase III study.

The Xilonix phase III study results were presented Saturday at a scientific meeting in Europe. XBiotech didn't post a copy of the Xilonix presentation to its website, choosing instead to only issue a press release containing limited details about the study results. XBiotech didn't respond to questions about the missing efficacy analyses.

XBiotech expects European regulators to approve Xilonix for colon cancer patients in the fourth quarter, based on the phase III study results submitted earlier this year. But if the messy, confused clinical data disclosed Saturday are any indication, a Xilonix approval in Europe is far from a sure thing.

With a market cap now exceeding $800 million, XBiotech cannot afford a Xilonix misstep. At Friday's close of $24.90, XBiotech shares have more than doubled in value this year.

The press release issued by XBiotech Saturday was mainly a rehash of Xilonix phase III study data first touted last fall.

Xilonix is a monoclonal antibody designed to target and shut down interleukin-1 alpha, a pro-inflammatory molecule. By eliminating IL-1 alpha in colon cancer patients, XBiotech believes Xilonix can stop tumor growth and improve cancer-related symptoms such as the loss of muscle mass, as well as fatigue and pain.
In the phase III study, treatment with Xilonix resulted in a 33% "clinical response rate" in patients with advanced colon cancer. This compared to a 19% "clinical response rate" in colon cancer patients treated with placebo, XBiotech said. The difference of 14 percentage points between the two arms of the study (a 76%

relative increase in response, XBiotech emphasizes) was statistically significant and achieved the primary endpoint of the study, according to XBiotech.

I put "clinical response rate" in quotes because the definition of the primary endpoint used by XBiotech in the Xilonix phase III study had nothing to do with measuring tumor response, or shrinkage, as is commonly used in cancer clinical trials.

In the XBiotech study, a colon cancer patient was deemed a responder if two conditions were met after eight weeks of treatment: 1) The patient had to maintain or gain lean body mass, measured by X-ray; and 2) the patient had to show an improvement in quality of life, captured by a questionnaire covering fatigue, pain and anorexia.

XBiotech said the primary endpoint of the Xilonix phase III study was designed in collaboration with European drug regulators as a novel way to measure the benefit of an anti-cancer drug in very sick colon cancer patients.

Yet a similar strategy was tried unsuccessfully three years ago by GTx (GTXI) , another small biotech company. Across two phase III studies, the GTx drug enobosarm improved lean body mass in lung cancer patients but was unable to improve muscle function. The enobosarm studies failed because both co-primary endpoints were not achieved. European regulators would not allow GTx to seek approval of enobosarm on improvement in lean body mass alone, nor would the U.S. Food and Drug Administration. ***The drug's development was discontinued***.

The GTx failure is important because XBiotech has offered conflicting descriptions of the Xilonix phase III study. ***On Saturday, the company said the phase III study utilized a single primary endpoint – "clinical response rate" -- assessing lean body mass and quality of life.***

However, as late as last fall, XBiotech was telling investors the phase III study was designed with co-primary endpoints: lean body mass and quality of life.

If European regulators follow the precedent set with GTx, XBiotech will need to show that Xilonix can produce separate, statistically significant improvements in lean body mass and quality of life in order to secure approval.

XBiotech didn't respond to questions seeking clarifications on the Xilonix study design or whether or not the drug was able to beat the control arm when lean body mass and quality of life were measured separately.

A second, phase III study of Xilonix is underway. This study, conducted mostly in the U.S. and still enrolling colon cancer patients, uses overall survival (Xilonix vs. placebo) as the primary endpoint.

Emphasis added.

34. On the release of the news, the Company's share price fell from an opening price on July 5, 2016, of $24.24 per share to a close at $15.78 per share on July 8, 2016, ***a drop of approximately 35%.***

D. Additional Misstatements

35. On July 9, 2016, *TheStreet* published a follow-up article with quotes from the Company's CEO Simard ("*TheStreet* July 9, 2016")[2]. The July 9, 2016, Article stated in pertinent part:

> The company's lead drug, Xilonix, is in Phase 3 trials in Europe for metastatic colorectal cancer patients. The results are expected to be revealed later this year. Xilonix is designed to block chronic inflammation associated with malignant tumor growth.
>
> "With that antibody, we were able to reduce cancer's negative effects on the body, suppress the growth of the tumor by blocking angiogenesis in the tube," said Simard. "***We are doing all these marvelous things at once with patients feeling better and recovering, which is a really novel thing to see in a cancer therapy.***"

Emphasis added.

36. The statements in paragraph 35 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the actual results were inconclusive; (2) the Company misrepresented the endpoint used in the European Study; (3) The Company's claim of a 76% increase in improvement was misleading and represented a relative improvement rate, (4) ultimately, the Companies' studies would not support the approval of the application with the EMA, and (5) as a

[2] *See* https://www.thestreet.com/story/13213704/1/xbiotech-ceo-explains-why-human-based-vaccines-are-superior.html.

result of the foregoing, Defendants' statements about its business and operations were materially false and misleading at all relevant times.

E. The Truth Continues to Emerge

37. On July 14, 2016, the European Society of Medical Oncology (ESMO) deemed the results from XBiotech's European Phase III reports unreliable ("ESMO Report")[3]. The ESMO Report Stated in pertinent part:

> LUGANO - The lively discussion which followed the presentation of 'A pivotal phase 3 Trial of MABp1 in advanced colorectal cancer' by Dr. Tamas Hickish during Session XIX: Colorectal Cancer, on Saturday, 2 July 2016, ***has highlighted several areas of debate which were not covered in the abstract submitted to the Congress' Scientific Committee nor its accompanying press release.***
>
> Professor Dirk Arnold from Instituto CUF de Oncologia in Lisbon, discussant of the abstract at the session and ESMO Executive Board Member, explains: "The abstract addressed a range of important issues, and therefore it was selected to be presented as an oral abstract. First of all, the study was addressing an unmet need in the treatment of patients with very late stage metastatic colorectal cancer having disease-related symptoms, and secondly, it uses an interesting, patient-relevant endpoint, with a new 'score' of symptom improvement parameters (which XBiotech wrote, and was developed together with an EMA working group). ***This is not entirely new, as a similar approach focusing on improvement of disease-related symptoms was used in the mid-1990s resulting in the registration of gemcitabine*** (a cancer drug used in pancreatic cancer, Burris et al., J Clin Oncol 1997), but of interest.
>
> "The conduct of the trial with a 2:1 randomization and a remarkable sample size presented was acceptable (although the estimation of the benefit and the consecutive sample size planning were not shown). ***However, a series of problems with the trial were highlighted at the presentation resulting in a lively discussion. Most importantly, the claim of a "76% increase in improvement…." is misleading (as it represents a relative improvement rate).***
>
> "The relevant numbers reported for symptom improvement after eight weeks according to this new scale are 33% of patients being treated with the new compound and 19% of patients in the placebo arm, so the difference of patients with symptom improvement with active treatment was only 14%. Interestingly, 19% of patients had symptom improvement without active treatment (in the trials´

[3] *See* http://www.esmo.org/Press-Office/Press-Releases/The-Debate-on-the-Phase-3-Trial-of-MABp1-Presented-at-the-18th-ESMO-World-Congress-of-Gastrointestinal-Cancer.

> placebo arm), relatively more than with the drug. ***Furthermore, no reference was made about when the onset of symptom relief during the eight weekly period was noted."***
>
> Continues Professor Arnold: "In my discussion about the abstract, I emphasised that the 'detailed analysis of clinical responders' with the new symptom-improvement score included all n=309 patients. However, the 'correlations with (radiographical?) disease stabilization' and 'numbers of patients with SAE´s' had only been done for 'responders' versus 'non-responders' – independent from treatment, so that 'responders' to placebo were also included in this analysis. The same applies to the 'overall survival' curve included – for which, however, only a subset of patients (N=175) was registered.
>
> "***In conclusion, the jury is still out on whether the study made sense but as the results do not bear close inspection, they also cannot be relied upon.*** It's not yet clear whether there is any benefit in translating this trial into practice."
>
> This follow up statement to the original press release incorporates the views of an ESMO key opinion leader; this would have ideally been shared at the Congress where we fast track news which is reviewed as soon as possible by an ESMO spokesperson.

Emphasis added.

38. On release of the news, the Company's share price fell from an opening price on July 14, 2016, of $18.06 per share to close at $15.39 per share, ***a drop of approximately 15%***.

39. On December 16, 2016, XBiotech filed a Form 8-K with the SEC, disclosing that it had received the Day 180 List of Outstanding Issues from the EMA (the "December 2016 Form 8-K"). The Form 8-K stated in pertinent part:

> On December 16, 2016, XBiotech Inc. (the "Company") announced that it has received the Day 180 List of Outstanding Issues (the "LoOIs") from the European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use (the "CHMP") in connection with the Company's Marketing Authorization Application (the "MAA") for Xilonix. Xilonix is an investigational drug candidate being evaluated for the treatment of advanced colorectal cancer.
>
> ***Major objections remain relating to clinical and quality matters. Clinical objections pertain primarily to benefit risk justification of the therapy and pharmacokinetics.*** Quality objections relate to qualification of the cell line used to produce the antibody and scaled down systems used to demonstrate robustness of the purification process as well as clarification of critical process controls. No

> objections remain regarding non-clinical aspects of the application. The Company believes the CHMP's requests are addressable. The Company plans to submit its responses to the LoOls within 60 days, in line with an updated regulatory timetable.

Emphasis added.

40. On release of the news, the Company's share price fell $2.85 from a closing price on December 15, 2016, of $12.83 per share to a close of $9.98 per share on December 16, 2016, ***a drop of approximately 22%***.

F. Further Misstatements

41. On February 22, 2017, XBiotech issued a press release disclosing Completed Dosing of Subjects in PK Study Being Conducted in Connection with the EMA (the "February 2017 Press Release"). The Company also attached the press release to a Form 8-K filed with the SEC ("February 2017 Form 8-K"). The Company made material false or misleading representations in the Press Release. The Company stated in pertinent part:

> AUSTIN, Texas, Feb. 22, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced that all subjects have been dosed in its pharmacokinetic (PK) study evaluating MABp1 half-life in healthy volunteers. This Phase I study will provide further PK data and will enable additional characterization of the PK of MABp1 at a 7.5mg/kg IV dose. ***Safety and tolerability will also be assessed.*** PK analyses at various time points ranging from pre-infusion to 336 hours post infusion will be collected. The study is on schedule to be completed as planned for the Company's upcoming regulatory submission.
>
> The Company previously reported it had been granted an additional 30 days to submit its responses to the Day 180 List of Outstanding Issues (D180LOI) by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) in connection with the Company's Marketing Authorization Application for Xilonix. This extension was granted as a result of a clarification meeting held recently between XBiotech and the EMA. The extension was granted in order to allow sufficient time for the Company to complete the PK study in healthy subjects. ***These new PK data are intended to address relevant technical questions in the D180LOI and will be included in the Company's response submission scheduled for March 22nd***.
>
> "We are happy to report the expeditious execution of this study, ***which will provide further PK data at multiple time points in the first 96 hours after***

> ***dosing***. This will enable additional and accurate characterization of the peak concentration, half-life and clearance, thus confirming PK is consistent with what would be expected from a monoclonal antibody," commented Michael Stecher, XBiotech's Medical Director. He further stated, "With these additional data in hand, we look forward to fully addressing the complete list of day 180 questions in March."

Emphasis added.

42. The statements in paragraph 41 above were as materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the additional above-mentioned PK Study would not assess outstanding clinical issues; (2) ultimately, the Companies' studies would not support the approval of the application with the EMA, and (3) as a result of the foregoing, Defendants' statements about its business and operations were materially false and misleading at all relevant times.

43. On March 3, 2017, XBiotech disclosed the registered direct offering of its common share, at a price of $13 per share, for an aggregate of approximately $31,000,000.

44. On March 8, 2017, XBiotech completed the registered direct offering of its common stock, with proceeds for the Company of approximately $31.6 million.

45. On March 27, 2017, XBiotech issued a press release announcing on-time submission to the EMA (the "March 2017 Press Release"). The Company made material false or misleading representations in the press release, in pertinent part:

> AUSTIN, Texas, March 27, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that it completed on time and confirmed receipt of its March 22, 2017 submission of responses to the remaining EMA queries related to its marketing authorization application. ***The Company feels***

> ***confident it has addressed all outstanding issues raised in the application for its candidate antibody therapy for the treatment of colorectal cancer***.

Emphasis added.

46. The statements in paragraph 45 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the actual results of the studies were inconclusive; (2) the Company misrepresented the endpoint used in the first European Study; (3) the Company's claim of a 76% increase in improvement was misleading and represented a relative improvement rate, (4) the Company misrepresented the impact of the additional PK Study, (5) ultimately, the Companies' studies would not support the approval of the application with the EMA, and (6) as a result of the foregoing, Defendants' statements about its business and operations were materially false and misleading at all relevant times.

G. <u>The Truth Is Finally Unveiled</u>

47. On April 20, 2017, after the market closed, XBiotech issued a press release disclosing Outcome of EMA's Oral Explanation Meeting (the "April 2017 Press Release"). The April 2017 Press Release stated in pertinent part:

> AUSTIN, Texas, April 20, 2017 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) announced today that ***the European Medicines Agency (EMA) rendered a negative "trend" vote after meeting with the Company to discuss the "Day 180 List of Outstanding Issues" related to the Company's marketing authorization application (MAA) for its candidate antibody for the treatment of colorectal cancer. A negative trend vote means it is unlikely that a positive Committee for Medicinal Products for Human Use (CHMP) opinion related to the Company's MAA will be attained at the formal decision vote scheduled in May, and that additional steps would need to be taken to potentially gain marketing approval***.

> At the Oral Explanation meeting, per EMA protocol, the Company gave a 20 minute presentation and had a Q&A session with CHMP members regarding the MAA for its candidate therapy to treat advanced colorectal cancer (data presented by the Company will be filed with the SEC in a Form 8-K and will be available on the SEC's website at *www.sec.gov*). The Oral Explanation format is intended to provide an opportunity for the Company to clarify data in support of marketing authorization.
>
> The key outstanding issues are related to clinical relevance of the therapy in the indication and quality assurance related matters. ***The meeting, however, focused on outstanding clinical relevance issues***.
>
> John Simard, President & CEO of the Company, stated, "We are disappointed by the outcome of the meeting. We believe that the data speak in a clear and resounding voice to clinical relevance of a new antibody therapy in advanced colorectal cancer. We believe that findings from our Phase III study show that we have developed an important endpoint and methodology to evaluate anti-cancer therapy in advanced stage disease and that our monoclonal antibody represents a breakthrough treatment in patients with advanced colorectal cancer. The EMA marketing authorization application procedure enables the appeal of negative decisions from the oral explanation. We may seek access to this process at the appropriate time."

Emphasis added.

48. On April 21, 2017, before the market opened, *TheStreet* published a follow-up article with quotes from the EMA's Oral Explanation Meeting ("*TheStreet* April 21, 2017")[4]. The article stated in pertinent part:

> Based on the poorly conducted clinical trial submitted by XBiotech to the EMA, Xilonix showed an ambiguous effect on the lean body mass and quality of life of colon cancer patients compared to a placebo. The drug did not shrink tumors, nor did it improve survival of the patients.
>
> XBiotech's efforts to shade Xilonix's clinical failings amounted to little more than hand waving when it mattered most. European regulators at the oral explanation meeting on Thursday were not fooled.
>
> *"**The clinical relevance of this rather small difference in favour of treatment with MABp1 is questioned and not considered compelling**,"* EMA's review team concluded.

[4] *See* https://www.thestreet.com/story/14096466/1/xbiotech-leaves-european-meeting-with-disappointed-over-colon-cancer-drug-rejection.html.

> [MABp1 is the scientific name of Xilonix. XBiotech used a new brand name for the drug, Hutruo, during Thursday meeting.]
>
> EMA reviewers also said this Thursday: "***Neither the sensitivity analyses of the individual co-primary endpoints, nor the analyses of secondary or exploratory endpoints provide any supportive evidence for efficacy in favour of MABp1***."
>
> A second phase III study of Xilonix colon cancer is underway, this one utilizing a much tougher overall survival primary endpoint. The likelihood of failure is high, it's just a matter of time.

Emphasis added.

49. On the release of the news, the Company's share price fell $6.79 from a closing price on April 20, 2017, of $17.02 per share, to a close of $10.23 per share on April 21, 2017, ***a drop of approximately 40%.***

H. Loss Causation and Economic Loss

50. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the Company's stock price, and operated as a fraud or deceit on acquirers of the Company's securities. As detailed above, when the truth about XBiotech's misconduct and its lack of operational and financial controls was revealed, the value of the Company's securities declined precipitously as the prior artificial inflation no longer propped up its stock price. The decline in XBiotech's share price was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market. The timing and magnitude of the common stock price decline negates any inference that the loss suffered by Plaintiff and other members of the Class was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, i.e., damages, suffered by Plaintiff and other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the Company's stock price and the subsequent significant decline in the value of the Company's

share, price when Defendants' prior misrepresentations and other fraudulent conduct was revealed.

51. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. Those statements were materially false and misleading through their failure to disclose a true and accurate picture of XBiotech's business, operations and financial condition, as alleged herein. Throughout the Class Period, Defendants publicly issued materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing XBiotech's securities to be artificially inflated. Plaintiff and other Class members purchased XBiotech's securities at those artificially inflated prices, causing them to suffer the damages complained of herein.

I. Scienter Allegations in Support of Exchange Act Violations

52. Collectively, the following factual allegations strongly support an inference of scienter on the part of Defendants. Further, Defendants' actions, intentions, and deliberately reckless conduct are imputed to the Company as a matter of law. Because of their key roles in the Company, the Individual Defendants caused XBiotech to act in the manner it did and perpetuate the material misrepresentations and omissions it made throughout the Class Period. Defendants acted with the requisite intent to establish liability under the Exchange Act. Their conduct with respect to XBiotech's statements was intentionally misleading and/or reckless with regard to the risk of investors being misled.

53. For the reasons stated above, the factual allegations strongly support an inference of scienter on the part of Defendants.

J. Presumption of Reliance; Fraud-on-the-Market

54. At all relevant times, the market for XBiotech securities was an efficient market for the following reasons, among others:

(a) XBiotech securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient market;

(b) During the Class Period, XBiotech common stock was actively traded, demonstrating a strong presumption of an efficient market;

(c) As a regulated issuer, XBiotech filed with the SEC periodic public reports during the Class Period;

(d) XBiotech regularly communicated with public investors via established market communication mechanisms;

(e) XBiotech was followed by securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(f) Unexpected material news about XBiotech was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

55. As a result of the foregoing, the market for XBiotech common stock promptly digested current information regarding Xbiotech from all publicly available sources and reflected such information in XBiotech's stock price. Under these circumstances, all purchasers of XBiotech common stock during the Class Period suffered similar injury through their purchase of XBiotech's securities at artificially inflated prices, and a presumption of reliance applies.

56. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to the ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security. Here, the facts withheld are material because an investor would have considered the Company's true net losses and adequacy of internal controls over financial reporting when deciding whether to purchase and/or sell stock in XBiotech.

K. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

57. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint.

58. To the extent that certain of the statements alleged to be misleading or inaccurate may be characterized as forward-looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

59. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading, and the "forward-looking statement" was authorized and/or approved by an executive officer of XBiotech who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any

plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

60. Plaintiff brings this action on behalf of all individuals and entities who purchased or otherwise acquired XBiotech common stock on the public market during the Class Period and were damaged, excluding the Company, Defendants, and each of their immediate family members, legal representatives, heirs, successors or assigns, and any entity in which any of the defendants have or had a controlling interest (the "Class").

61. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, XBiotech securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by XBiotech or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of August 8, 2017, Xbiotech had 35,419,772 outstanding shares of common stock. Upon information and belief, these shares are held by thousands if not millions of individuals located geographically throughout the country and possibly the world. Joinder would be highly impracticable.

62. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' respective wrongful conduct in violation of the federal laws complained of herein.

63. Plaintiff has and will continue to fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

64. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' respective acts as alleged herein;

(b) whether Defendants acted knowingly or with deliberate recklessness in issuing false and misleading financial statements;

(c) whether the price of XBiotech common stock during the Class Period was artificially inflated because of Defendants' conduct complained of herein; and

(d) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

65. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

Violation of Section 10(b) and Rule 10b-5 Against All Defendants

66. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

67. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (2) cause Plaintiff and other members of the Class to purchase XBiotech common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, each Defendant took the actions set forth herein.

68. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for XBiotech common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

69. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of XBiotech as specified herein.

70. Defendants employed devices, schemes, and artifices to defraud while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of XBiotech's value and performance and continued substantial growth, which included the making of, or participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about XBiotech and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business that operated as a fraud and deceit upon the purchasers of XBiotech securities during the Class Period.

71. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (1) the Individual Defendants were high-level executives, directors, and/or agents at the Company during the Class Period and members of the Company's management team or had control thereof; (2) each Individual Defendant, by virtue of his responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's financial condition; (3) each Individual Defendant enjoyed significant personal contact and familiarity with the other Individual Defendant and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (4) each Individual Defendant was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

72. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing XBiotech's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's financial condition throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

73. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of XBiotech's common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of XBiotech's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired XBiotech's common stock during the Class Period at artificially high prices and were or will be damaged thereby.

74. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the

other members of the Class and the marketplace known the truth regarding XBiotech's studies on Xilonix, which was not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their XBiotech common stock, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices that they paid.

75. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

76. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

77. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of securities giving rise to the cause of action.

COUNT II

The Individual Defendants Violated Section 20(a) of the Exchange Act

78. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

79. Simard and Han acted as controlling persons of Xbiotech within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, agency, ownership and contractual rights, and participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements that Plaintiff contends are false and misleading. The Individual Defendants were

provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to have been misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

80. In particular, each Defendant had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

81. As set forth above, XBiotech, the Individual Defendants each violated Section 10(b), and Rule 10b-5 promulgated thereunder, by their acts and omissions as alleged in this Complaint.

82. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

83. This action was filed within two years of discovery of the fraud and within five years of each plaintiff's purchases of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

(a) Determining that this action is a proper class action, certifying Plaintiff as class representative under Federal Rule of Civil Procedure 23 and Plaintiff's counsel as class counsel;

(b) Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained

as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

(d) Granting extraordinary equitable and/or injunctive relief as permitted by law; and

(e) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff hereby demands a jury trial.

DATED: October 26, 2017.

Respectfully submitted,

/s/ Thomas E. Bilek

Thomas E. Bilek
Texas Bar No. 02313525
THE BILEK LAW FIRM, L.L.P.
700 Louisiana, Suite 3950
Houston, TX 77002
(713) 227-7720

Attorneys for Plaintiff

OF COUNSEL:

Eduard Korsinsky
LEVI & KORSINSKY LLP
30 Broad Street, 24th Floor
New York, NY 10004
Tel: (212) 363-7500
Fax: (212) 363-7171
Email: ek@zlk.com